K063484

DEC 2 2 2006

510(K) SUMMARY

SUBMITTER'S NAME:	InterMed Advisor's, Inc.
CONTACT INFORMATION:	828 Massachusetts Avenue Arlington, MA 02476 Phone: (781) 648-4935 Fax: (866) 639-3935
CONTACT PERSON:	Christina Vullo, Director of Regulatory Affairs
DATE PREPARED:	September 29, 2006
TRADE NAME:	Patient Data Handler & Devices (PDH&D)
COMMON NAME:	Patient Data Handler & Devices (PDH&D)
CLASSIFICATION NAME:	Radiofrequency Physiological Signal Transmitter and Receiver (21 CFR 870.2910, Product Code DRG)
PREDICATE DEVICES:	Health Hero Network, Health Buddy Appliance, #K050567 (and K060843) A&D Medical UA-767PBT Digital Blood Pressure Monitor, # K043217
INDICATIONS FOR USE:	The PDH&D is indicated for use in non-clinical settings to collect and transmit historical patient data to healthcare professionals to help support effective management of their patients.
DEVICE DESCRIPTION:	The PDH&D includes the Patient Data Handler (PDH) and peripheral biometric devices for the monitoring of chronic diseases. It is intended to be used as a communication tool, enabling Healthcare Providers and Care Managers to receive historical patient data including blood glucose levels, blood pressure, weight, peak flow volume, and oxygen saturation levels. Providers may review patient information over the InterMed Patient Provider Online Tool (IPPOT). The PDH&D is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment. All patient medical diagnosis and treatment are to

be performed under the supervision and oversight of a healthcare professional.

TECHNOLOGICAL CHARACTERISTICS:

The PDH&D securely transmits physiological patient data from biometric devices to InterMed's Data Center. The data transfer between peripheral devices and the PDH occurs via Bluetooth Radio. This is the same platform used by the A&D Medical UA-767PBT Digital Blood Pressure Monitor. The data transfer between the PDH and the Data Center occurs via a phone line or cable modem. The Data Center may generate session content that is downloaded onto individual PDH units. The IPPOT is available for viewing by Care Managers and Care Providers over a secure website. It requires a username and password for security purposes.

NONCLINICAL TESTS:

Nonclinical tests were performed to ensure the safety and efficacy of the PDH&D.

CONCLUSIONS:

The results of Verification and Validation activities have indicated that the PDH&D performs according to requirements and specifications and represents a residual minor risk to the user. They support InterMed's determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2006

Intermed Advisors, Inc.
c/o Daniel W. Lehtonen
Director of Regulatory Affairs
828 Massachusetts Avenue
Arlington, MA 02476

Re: K063484
Trade/Device Name: Patient Data Handler and Devices (PDH&D)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: December 7, 2006
Received: December 8, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

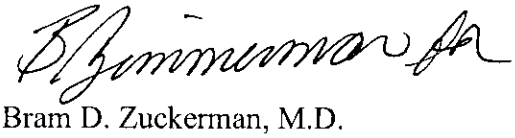
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063484 ~~pending~~

Device Name: Patient Data Handler & Devices (PDH&D)

Indications for Use:

The PDH&D is indicated for use in non-clinical settings to collect and transmit historical patient data to healthcare professionals to help support effective management of their patients.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063484

Prescription Use __X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)